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Subject Environmental Defense comments on C.I. Pigment Violet 19,  
C.I. Pigment Red 122 and Dihydroquinacridine

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Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for **C.I. Pigment Violet 19, C.I. Pigment Red 122 and Dihydroquinacridine.**

The Quinacridine Committee of the Color Pigments Manufacturers Association, Inc., in response to EPA's High Production Volume (HPV) Chemical Challenge, has submitted a test plan and robust summaries for C.I. Pigment Violet 19, C.I. Pigment Red 122 and Dihydroquinacridine, CAS#s 1047-16-1, 980-26-7, and 5862-38-4, respectively. As stated in this submission, these pigments have very similar structures. This submission offers a rationale for considering them together and uses the term, "Test Plan Grouping". We agree that they should be considered together and suggest they be considered a chemical category as directed by HPV guidelines.

Both the test plan and robust summaries portions of this submission are poorly written and provide minimal information. Dihydroquinacridine is said to be used as a site-limited intermediate; however, the pigments are said to be used in numerous paints and plastics. Thus, the pigments would be expected to pose significant potential for human and environmental exposure. However, potential sources of release or measures to limit release are not mentioned in this submission.

Virtually all of the data described to address the SIDS elements for the physicochemical properties and environmental fate of these compounds were derived by computer estimation. We defer to the EPA any decision regarding the quality and acceptability of these estimates to address the required SIDS elements. The test plan states that the SIDS elements for ecotoxicity are addressed by "acceptable studies" or "acceptable estimates;" however, results of these studies or estimates are not further discussed in the test plan.

The preparers of this submission appear to have a very liberal interpretation of the systematic classification of scientific studies as described by Klimisch et al. and quoted on page 9 of this submission. The following are two of the more glaring examples of studies that are, but should not be, classified "Reliable without restriction".

- A. On page 23 is a description of a study of daphnia reproduction that fails to provide most of the critical data, including the dose used.
- B. On page 30 of the robust summaries is a study described as a "Repeated Dose Toxicity Test" that states that a single dose was used and fails to provide other critical data.

We would suggest the preparer(s) of this submission reconsider its claims as to the reliability of these and other studies in light of the guidelines reproduced in the section on "Evaluation of data for Quality and acceptability" on page nine of the test plan.

Under "Environment," the cited study of toxicity to daphnia is not only poorly documented, as described above, it focuses on reproduction, and provides little information on toxicity. Also, it is stated in the robust summaries that a study of toxicity to plants cannot be determined because these chemicals are so intensely colored that they will absorb all light necessary for algal growth. This rationale seems inconsistent with earlier statements in the test plan and robust summaries that indicate these chemicals are insoluble. If these chemicals are truly insoluble they would not color the water. If they are soluble to some degree, there is a concentration, however low, at which algal growth can continue.

According to data described in the test plan and robust summaries, these compounds have little acute toxicity. We agree that, based on the limited data described, that appears to be the case. We also agree that this is most probably attributed to the fact that these chemicals are so sparingly soluble that they are not absorbed from the gastrointestinal tract. This assumption is supported by studies of absorption and excretion. If these chemicals are truly very poorly absorbed, then they might be assumed to be relatively safe; however, direct evidence addressing the required SIDS elements for mammalian toxicity is limited. Cited studies with animals appear to have been poorly designed, not conducted under GLP and generally poorly reported in this submission. A glaring example of failure to address the required SIDS elements is seen in the study proposed to address reproductive toxicity. The study cited did not involve mammals; rather, it used daphnia and, as mentioned above, should not be considered an acceptable study. No data are provided for the study of developmental toxicity.

Specific Comments:

1. The chemical structural formula of dihydroquinacridine provided in the test plan should be large enough for the reader to clearly discern the entire structure.
2. A typo on the first page of the robust summaries indicates the data are reported for C. I. Pigment "Violet" 122 rather than Red 122.
3. Review of data in the robust summaries would be greatly facilitated if the common names of these chemicals were provided along with the chemical names in each of the studies reported.
4. Page 23 of the robust summaries is incorrectly formatted.

In summary, both the test plan and robust summaries of this submission are poorly written and provide minimal information regarding C.I. Pigment Violet 19, C.I. Pigment Red 122 and dihydroquinacridine. Many of the studies described are quite old, were poorly designed and were not conducted under GLP. Therefore, this submission does not meet the requirements of the HPV Challenge.

Thank you for this opportunity to comment.

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